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y: Winsome A St. Rose

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Martin Dugas, et al. ) EXAMINER: Unassigned

SERIAL NO.: 10/575,635 ) ART UNIT: Unassigned

PCT FILING DATE: NOVEMBER 4, 2004 ) Confirmation No. N/A

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## INFORMATION DISCLOSURE STATEMENT

Mail Stop Disclosure. Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicant submits herewith a Form-1449, in compliance with the duty of disclosure requirements of 37 C.F.R. §1.56, 1.97 and 1.98, listing accompanying documents that may be considered material to the examination of this application. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits, whichever event occurs last. No certification or fee is therefore required under 37 C.F.R. § 1.97(b). However, should the Commissioner determine that fees are due in order for the Information Disclosure Statement to be considered at this stage, the Commissioner is hereby authorized to charge any fee deficiency, or credit any overpayment, to Deposit Account No. 50-0812.

Applicants wish to provide the USPTO with an electronic copy of WO 03/039433A2, which is in excess of 2,900 pages.

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This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested.

Respectfully submitted,

Date: 9

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U.S. Department of Commerce Patent and Trademark Office					Atty. Docket No. 22331-US   Serial No. 10/575,635						
LIST OF INFORMATION CITED BY APPLICANT (Use segrature is in necessary)				Applicants: Martin Dugas, et al.							
U.S. PAT				International Filing Date: Nov 4, 2004				Gro	up: N/A		
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INITIAL	1	5,210,015	05/11/93		Gelfand, et al	435	6		08/06/90		
	2	5,445,934	08/29/95		Fodor, et al	435	6		09/30/92		
	3	5,487,972	01/30/96		Gelfand, et al	435	6		01/05/93		
	4	5,700,637	12/23/97		E. Southern	435	6		04/19/94		
	5	5,744,305	04/28/98		Fodor, et al	435	6		06/06/95		
	6 5,804,375		09/08/98		Gelfand, et al	435	6		04/25/95		
	7	5,945,334	08/31/99	<del></del>	Besemer, et al	435	287.2		06/07/95		
	8 -	6,174,670 B1	01/16/01		Wittwer, et al	435	6		06/04/97		
	9	2003/0138793 A1	07/24/03		Su, et al	435	6		06/10/02		
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	11 12 13 14	DOCUMENT NUMBER  0 373 203 B1  0 619 321 B1  1 043 676 A1  WO 92/02638  WO 03/039443 A2  WO 2005/043161 A3  EP2004/012463	PUBLICA DAT 08/31/94 01/07/90 10/11/00 02/20/92 05/15/03	ATION	EP EP EP PCT		SUBCLAS	SS 7	TRANSLATION		
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	11 12 13 14 15 16	DOCUMENT NUMBER  0 373 203 B1  0 619 321 B1  1 043 676 A1  WO 92/02638  WO 03/039443 A2  WO 2005/043161 A3  EP2004/012463 Search Report  OTHER ART (In Alizadeh, A., et al., 1999, "T Gene Expression in Norma Biology, Volume LXIV, Col Brown, M., et al., 2000, "Kn machines, PNAS, 97(1):262  Dugas, M., et al., 2001, "A c microarray data with clinica Dugas, M., et al., 2002, "Im  Furey, T., et al., 2000, "Sup	PUBLICA DAT 08/31/94 01/07/90 10/11/00 02/20/92 05/15/03 05/12/05 06/09/05 cluding A The Lymphot and Maligned Springs H owledge-based informatic pact of Interpret vector	uthor, ochip: A nant Lyr arbor La sed anal sive leuk on, cyto grating of	EP EP EP PCT PCT PCT PCT PCT PCT Pitle, Date, Pertin Specialized cDNA Minphocytes", Cold Spriboratory Press, pp 71-ysis of microarray genemia database: integra morphology and imm Clinical and Genetic Is e classification and val	ent Pages, croarray for ngs Harbor 78 e expression ation of cyto aunophenot information	Etc.) the Genomi Symposium data by usir genetics, mo vping", Leuk T, In Silico Bio	c-scale on Quang supp lecular emia, 1: ology, 2	Analysis of antitative Fort vector genetics and 5:1805-1810 :383-391		
	11 12 13 14 15 16 17 18 19 20	DOCUMENT NUMBER  0 373 203 B1  0 619 321 B1  1 043 676 A1  WO 92/02638  WO 03/039443 A2  WO 2005/043161 A3  EP2004/012463 Search Report  OTHER ART (In Alizadeh, A., et al., 1999, "T Gene Expression in Normal Biology, Volume LXIV, Coll Brown, M., et al., 2000, "Kn machines, PNAS, 97(1):262  Dugas, M., et al., 2001, "A c microarray data with clinical Dugas, M., et al., 2002, "Im	PUBLICA DAT  08/31/94  01/07/90  10/11/00  02/20/92  05/15/03  05/12/05  06/09/05  cluding A The Lymphol and Malign of Springs H owledge-based information pact of Interport vector of Bioinformation of Bioinformatics and Springs H owledge-based information pact of Interport vector of Bioinformatics o	uthor, ochip: A nant Lyn arbor La sed anal sive leuk on, cyto grating of	EP EP EP PCT PCT PCT PCT PCT PCT Pitle, Date, Pertine Specialized cDNA Minphocytes", Cold Spriboratory Press, pp 71-ysis of microarray genemia database: integramorphology and immiclinical and Genetic I e classification and val 10):906-914	ent Pages, croarray for ngs Harbor 78 e expression unophenot nformation'	Etc.) the Genomi Symposium data by usin genetics, mo yping", Leuke The Genomi	c-scale on Quang supp lecular emia, 1: ology, 2 amples	Analysis of antitative fort vector genetics and 5:1805-1810 (383-391) using		
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Attorney Docket: 22331-US Serial No. 10/575,635 Page 2 of 2

24	Haferlach, T., et al., "Abstract: The Diagnosis of 14 Specific Subtypes of Leukemia Is Possible Based on Gene Expression Profiles: A Study on 263 Patients with AML, ALL, CML, or CLL", Blood, 100, Abstract 523					
25	Harlow, E., et al, 1988, "Antibodies A Laboratory Manual", Cold Spring Harbor Laboratory					
26	Complex Aberrant Karyotype", Blood, 100, Abstract 1236					
27	Koehler, G., et al., 1975, "Continuous cultures of fused cells secreting antibody of predefined specificity", <i>Nature</i> . 256:495-497					
28	Kohlmann, A., et al., 2002, "Abstract: A Simplified and Partially Automated target Preparation Method for Gene Expression Profiling", <i>Blood</i> , 100, Abstract 4287					
29	Kohlmann, A., et al., 2002, "Abstract:: A Gene Expression Study of 59 Acute Myeloid Leukemia (AML) Patients with recurrent Cytogenetic Abnormalities", <i>Blood</i> , 100, Abstract 1205					
30	Kohlmann, A., et al., 2002, "Abstract: Gene Expression Profiles of t(11q23)/MLL Positive ALL and AML", <i>Blood</i> , 100l <u>11</u> ): Abstract No. 30.					
31	Kohlmann, A., et al., 2003, "Molecular Characterization of Acute Leukemias by Use of Microarray Technology", Genes, Chromosomes & Cancer, 37:396-405					
32	Liu, G., et al., 2003, "NetAffx: Affymetrix probesets and annotations", Nucleic Acids Research, 31(1):82-86					
33	Sambrook, J., et al., 1989, "Molecular Cloning A Laboratory Manual Second Edition", Cold Spring harbor Laboratory Press,					
34	Schoch, C., et al., 2002, "Acute myeloid leukemias with reciprocal rearrangements can be distinguished by specific gene expression profiles", <i>PNAS</i> , 99(15):10008-10013					
35	Schoch, C., et al., 2001, "AML with recurring chromosome abnormalities as defined in the new WHO-Classifications: Incidence of subtypes, additional genetic abnormalities, FAB subtype and age distribution in an unselected series of 1897 cytogenetically and moleculargenetically analyzed AML", Blood, 98(11 part 1):457a-458a					
36	Schoch, C., et al., 2002, "Abstract: AML with complex Aberrant Karyotype can be distinquished from all other AML subtypes by gene expression profiles and are characterized by higher expression of genes involved in DNA repair", <i>Blood</i> , 100, Abstract No. 1204					
37	37 Storey, J., et al., 2003, "Statistical significance for genomewide studies," PNAS, 100(16):9440-9445					
38	Tipping, A., et al., 2003, "Comparative gene expression profile of chronic myeloid leukemia cells innately resistant to innately mesylate,", Experimental Hematology, 31:1073-1080					
EXAMINER	DATE CONSIDERED					
	al if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in considered. Include copy of this form with next communication to applicant.					